UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,550	06/28/2001	Albert Collinson	BBC-083 A US	6240

7590 05/04/2004

KENNETH P. ZWICKER
ABBOTT BIORESEARCH CENTER
100 RESEARCH DRIVE
WORCESTER, MA 01605

EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/894,550	COLLINSON ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *07 April 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: *10*.

   Claim(s) rejected: *1-4,9,12-31 and 89-95*.

   Claim(s) withdrawn from consideration: *5-8, 11, 32-88*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 4, 12-15, and 19-24 as lacking enablement for antibodies that are not fully mouse is overcome by Applicant's argument that the claims wou7ld encompass only the modified antibodies.

Continuation of 5. does NOT place the application in condition for allowance because: With respect to the rejjection of claims 1-4, 12-14, 16-30, 31, and 89-95 under 35 U.S.C. 103(a), Applicant argues that Luger do not teach or suggest the use of other means to produce antibodies and that the other references do not teach Applicant's method of making a dual-specific antibody. Applicant argues that there is no suggestion or motivation to combine the references. Applicant argues that the disclosure of IL-1 as involved in inflammation combined with general references is not a "clear and particular teaching, suggestion, or motivation" to make the claimed antibodies. Applicant indicates that the Examiner's reasoning involves "patchwork compilation" and hindsight reasoning.
Applicant's arguments have been fully considered but have not been found to be persuasive. To attack the references indivicually is, as was stated in the previous office action, improper; what is relevant is what is taught by the comibnation of the references, With regard to motivation, as was stated in the previous office action and the telephone interview of 16 December 2003, interleukin 1 is a modulator of inflammatory reactions. It is a proinflammatory molecule involved in such conditions as sepsis and has further been the target of therapeutic agents aimed at inhibiting its action, as would have been well know to one of ordinary skill in the art at the time of Applicant's invention. Thus no "pathwork compilation" or use of Applicant's disclosure is required for motivation to inhibit its action.

With respect to the rejection of claims 1-4, 9, 12-31, and 89-95 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims, Applicant argues that biotechnology requires extensive experimentation and that such experimentation is not undue. Appicant argues that the specification teaches the necessary techniques and that the Examiner "would deny Applicants claim to their invention simply for disclosing inoperative embodiments".
Appicant's arguments have been fully considered but have not been found to be persuasive. The antibodies dislcosed by Appicant and by the prior art appear to be against the same region, but Applicant is claiming dual-specific antibodies against all possible eptiopes. That those antibodies against other epitopes did not work indicates that Applicant has not in fact enabled a genus of dual specific antibodies, but only antibodies against the particular epitope taught in the art and which Applicant has also found to be useful. Thus it is not merely a matter of a few or even many inoperative embodiments; Applicant's specification fails to provide any guidance to indicate that any epitope other than what is already known in the art would work That Applicant has provided a number of art-standard techniques does not enable an invention. Applicant's parallel with transfection is not relevant. With an epitope known to be capable of generating a useful antibody, failure to generate at useful antibody some or even most of the time would not indicate that the invention was not enabled; as Applicant states, the success rate of such processes may be low. However, Applicant is not claiming antibodies against epitopes known to work. Applicant is claiming any and and all dual-specific antibodies and has not provided any guidance to indicate that any eptiopes other than that taught by the prior art would be able to generate such antibodies
Applicant argues that the objection to claim 10 should be withdrawn because all claims are allowable. The objection to claim 10 is maintained for the reasons set forth above.